

In re Application of: Anthony FUTERMAN et al.
Serial No.: 10/552,287
Filed: January 4, 2007
Advisory Action Mailing Date: July 24, 2009

Examiner: David J. STEADMAN
Group Art Unit: 1656
Attorney Docket: 30227

REMARKS

Reconsideration of the above-identified application in view of the amendments above and the remarks following is respectfully requested.

Claims 123, 124, 129, and 133-156 are pending in the Application. Claims 139-156 have been withdrawn from consideration. Claims 123, 124, 129 and 133-138 have been rejected.

Claims 123, 124, 129 and 133-138 have been rejected under 35 U.S.C. §112. Claims 133-137 have been rejected under 35 U.S.C. §102(a) as anticipated by Dvir et al. Claim 138 has been rejected under 35 U.S.C. §103(a) as being obvious over Dvir et al. Claims 123, 129, 133-136 and 138 have been amended herewith. New claims 157 and 158 have been added herewith.

The Application now comprises, after amendments, claims 123, 124, 129, 133-158, of which claims 123, 129, 139 and 153-156 are in independent form.

Declarations

Applicants' Declaration under 37 C.F.R. §1.132 asserting that Andrew A. MCCARTHY was not a co-inventor of the above-identified Application is provided herewith for entrance into the record and consideration by the Examiner.

Applicants' Petition to Correct Inventorship under 37 C.F.R. §1.148(a), requesting removal of Svetlana ADAMSKY as a co-inventor of the above-identified Application, and accompanying fees, Declarations and Statements, are also provided herewith for entrance into the record and consideration by the Examiner.

Claim to Priority

While traversing the Examiner's assertions, Applicants have chosen to amend the domestic priority paragraph with regard to US Provisional Application No. 60/463,049, in accordance with the Examiner's requirements.

Regarding foreign priority, the Examiner has acknowledged that PCT Application No. PCT/IL2004/000335 clearly provides support for the subject-matter of claims 123, 124, 129 and 133-138, and that Israel Patent Application No. 156273 clearly provides support for the subject-matter of claims 123, 124 and 129.

New claims 157 and 158 relate to the glucocerebrosidase solutions of claim 129, having normal enzymatic activity (157) and in a pharmaceutical composition for

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treating Gaucher's disease (158). Applicants submit that claims 157 and 158 are fully supported in the disclosure of Israel Patent Application No. 156273, as indicated by the Examiner (*see* Final Office Action dated April 8, 2009, pages 4 and 5), and thus derive benefit of priority therefrom (June 2, 2003).

Specification/Informalities

Applicants have amended the Specification to include the substitute Sequence Listing paper copy filed on January 4, 2007, as required by the Examiner (*see* "In the Specification", *supra*).

35 U.S.C. §112, First Paragraph Rejections

The Examiner has rejected claims 123, 124, 129 and 133-138 under 35 U.S.C. §112, First Paragraph, as failing to comply with the written description requirement. The Examiner's rejections are respectfully traversed. Claims 123, 129, 133-136 and 138 have now been amended.

Regarding claims 129 and 133-138, claim 129, and claims dependent therefrom have now been amended to recite "...glucocerebrosidase solution..." in place of "glucocerebrosidase preparation...", thereby limiting the claim to non-crystalline glucocerebrosidase. Support for such an amendment is found throughout the instant specification, for example, Example 1.

"Crystals were obtained via the hanging-drop technique at room temperature using a drop composed of 1.5 microliters of the 10 mg/ml glucocerebrosidase solution and 1.5 microliters of mother liquor [1 molar (NH₂)₂SO₄ pH 4.6, 0.17 molar guanidine hydrochloride, 0.02 molar KCl, 0.1 molar sodium acetate buffer, pH 4.6]."(page 80, lines 17-20 of the instant specification)

Regarding claims 123, 124, 129 and 133-138, claims 123 and 129 have now been amended to recite the phrase "...consisting of the amino acid sequence as set forth in SEQ ID NO: 1...", in place of the phrase "...having the the amino acid sequence...", thereby further defining the claimed "glucocerebrosidase molecule".

Regarding the predictability of crystallization, Applicants maintain that claims 123 and 129 read on clearly defined glucocerebrosidase polypeptide molecules,

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having defined glycosylation pattern (glycosylated at asparagine 19 and unglycosylated at Asn59, Asn146 or Asn270) which can form crystal structures having characteristic structural coordinates, space group and unit cell dimensions.

Regarding claim 134, amended claim 134 now reads on the glucocerebrosidase solution, wherein the glycosylated asparagine 19 has at least one exposed mannose residue, thus further clarifying the scope of amended claim 134.

Thus, Applicants submit that now amended claims 123 and 129, and claims dependent therefrom read on clearly defined glucocerebrosidase polypeptide molecules, which can form crystal structures having characteristic structural coordinates, space group and unit cell dimensions, which glucocerebrosidase polypeptides and crystals are supported, and thus fully enabled throughout the instant specification.

102(a)/103(a) Rejections:

Dvir et al. (EMBO Reports, 2003; 4:704-709)

The Examiner has rejected claims 133-138 under 35 U.S.C. §102(a) and §103(a) as anticipated by [102(a)] or obvious [103(a)] over Dvir et al. The Examiner's rejection is respectfully traversed. Claims 123, 129, 133-136 and 138 have now been amended.

Applicants are attaching an executed Declaration under 37 C.F.R. §1.132, in which the Applicants assert that the co-author, Andrew A MCCARTHY, identified along with Hay DVIR, Michal HAREL, Lilly TOKER, Israel SILMAN, Anthony H. FUTERMAN and Joel L. SUSSMAN in an article entitled *X-Ray Structure of Human Acid-Glucosidase, the Defective Enzyme in Gaucher Disease*, published on June 3, 2003 (online publication) in "EMBO Reports" in Vol. 4, Issue 7, at pages 704-709, was identified as a co-author on said article for his collaborative efforts operating under our guidance and direction, and was not a co-inventor of the above-identified application. The Declaration further asserts that the only inventors of the invention are Hay DVIR, Michal HAREL, Lilly TOKER, Israel SILMAN, Anthony H. FUTERMAN and Joel L. SUSSMAN.

Applicants also are attaching an executed Petition under 37 C.F.R. §1.148(a), and accompanying Declarations and Statements asserting that Svetlana ADAMSKY was included as co-inventor of the present Patent Application erroneously, without

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deceptive intent, and requesting removal of Swetlana ADAMSKY as a co-inventor of the above-identified Application.

As such, the above-identified publication cited by the Examiner to reject claims 133-138 is not a publication of "another", but rather Applicants' own publication, which was published less than a year before Applicants' filing date, and thus is not proper prior art thereagainst.

Thus, Applicants respectfully request withdrawal of the rejection on the basis of §102(a)/§103(a).

In view of the foregoing amendments and remarks, pending claims 123, 124, 129, 133-138 and new claims 157 and 158 are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Respectfully submitted,



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Date: August 10, 2009

Enclosures:

- Request for Continued Examination (RCE);
- Petition for Extension of Time (One Month);
- Petition under 37 C.F.R. §1.48(a);
- Executed Statement of Facts to Correct Inventor's Names;
- Assignee's Consent to Correction of Inventorship;
- Executed Declaration under 37 C.F.R. §1.132;
- Executed Substitute Declaration and Power of Attorney; and
- Substitute Sequence Listing paper copy and Floppy Disc.